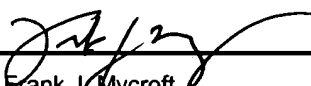
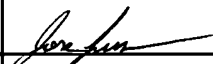


OFFICE TRANSMITTAL FORM JUL 18 2006 (to be used for all correspondence after initial filing) PATENT & TRADEMARK OFFICE	Application Number	10/669,099
	Filing Date	September 22, 2003
	First Named Inventor	Gorfine, Stephen R.
	Art Unit	1655
	Examiner Name	Tate, Christopher Robin
	Attorney Docket Number	010692-004532US
Total Number of Pages in This Submission		9

ENCLOSURES (Check all that apply)		
<input checked="" type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment/Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input checked="" type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Reply to Missing Parts/ Incomplete Application <input type="checkbox"/> Reply to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation <input type="checkbox"/> Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____ <input type="checkbox"/> Landscape Table on CD	<input type="checkbox"/> After Allowance Communication to TC <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): Duplicate Fee Transmittal (1 page); References (28); Return Postcard.
Remarks: The Commissioner is authorized to charge any additional fees to Deposit Account 20-1430.		
SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT		
Firm Name	Townsend and Townsend and Crew LLP	
Signature		
Printed name	Frank J. Mycroft	
Date	July 13, 2006	Reg. No. 46,946

CERTIFICATE OF TRANSMISSION/MAILING			
I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below.			
Signature			
Typed or printed name	Jose Luna	Date	July 13, 2006

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to:

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

On July 13, 2006

TOWNSEND and TOWNSEND and CREW LLP

PATENT
Attorney Docket No.: 010692-004532US



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Gorfine, Stephen R.

Application No.: 10/669,099

Filed: September 22, 2003

For: NITRIC OXIDE DONOR
COMPOSITION AND METHOD FOR
TREATMENT OF ANAL DISORDERS

Confirmation No.: 1846

Examiner: Tate, Christopher Robin

Art Unit: 1655

SUPPLEMENTAL INFORMATION
DISCLOSURE STATEMENT UNDER
37 CFR §1.97 and §1.98

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

The references cited on the attached forms PTO/SB/08A and PTO/SB/08B are being called to the attention of the Examiner.

As the Examiner will note, the Declarations of Peter B. Loder and David Z. Lubowski contain many exhibits. In an effort to avoid burdening the Examiner with duplicative information, copies of all documents cited in the above declarations which have already been submitted in an Information Disclosure Statement are not cited on the attached forms and are not

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provided herewith. However, Applicant would be happy to supply the Examiner with additional copies of these documents upon request. Copies of all other cited references are enclosed.

It is respectfully requested that the cited references be expressly considered during the prosecution of this application, and the references be made of record therein and appear among the "references cited" on any patent to issue therefrom.

As provided for by 37 CFR §1.97(g) and (h), no inference should be made that the information and references cited are prior art merely because they are in this statement and no representation is being made that a search has been conducted or that this statement encompasses all the possible relevant information.

This IDS is being filed before the mailing date of the final Office Action or Notice of Allowance.

Please charge the IDS fee of \$180 to Deposit Account No. 20-1430. Please deduct any additional fees from, or credit any overpayment to, the above-noted Deposit Account.

Respectfully submitted,



Frank J. Mycroft
Reg. No. 46,946

TOWNSEND and TOWNSEND and CREW LLP
Two Embarcadero Center, Eighth Floor
San Francisco, California 94111-3834
Tel: 925-472-5000
Fax: 925-472-8895
FJM:jvl

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 1 of 4

Complete if Known

Application Number	10/669,099
Filing Date	September 22, 2003
First Named Inventor	Gorfine, Stephen R.
Art Unit	1655
Examiner Name	Tate, Christopher Robin
Attorney Docket Number	010692-004532US

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number Kind Code ² (if known)			

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document			Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³	Number ⁴	Kind Code ⁵ (if known)				
	1.	ZA	9500511	A	03-11-1996	Koren Lab Pty Ltd		<input type="checkbox"/>
								<input type="checkbox"/>

Examiner
SignatureDate
Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² Kind Codes of U.S. Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	10/669,099
				Filing Date	September 22, 2003
				First Named Inventor	Gorfine, Stephen R.
				Art Unit	1655
				Examiner Name	Tate, Christopher Robin
Sheet	2	of	4	Attorney Docket Number	010692-004532US

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²	
	2.	ANONYMOUS, "ASCRS Registrants: 92nd Annual Convention - May 2-7, 1993, Hyatt Regency Chicago, Chicago, IL," List of Registrants, 34 pages [Exhibit PBL-9 to the Loder Declaration]	<input type="checkbox"/>	
	3.	ANONYMOUS, "Royal Australian College of Surgeons and Australian and New Zealand College of Anaesthetists Annual Scientific Congress- Adelaide 1993: Statistics at 14/5/93" and "A.S.C. Adelaide 1993 Scientific Programme: 10-14 May, 1993" Proceedings excerpts, 5 pages [Exhibit PBL-11 to the Loder Declaration]	<input type="checkbox"/>	
	4.	BROOKES, S., "Statutory Declaration: In the Matter of Australian Patent Application No. 708694 in the Name of Cellegy Australia Pty Ltd -and- In the Matter of Opposition thereto by Peter Loder," 2 pages, October 11, 2000	<input type="checkbox"/>	
	5.	CRISTOFANI, K., "Anal fissures treated: Topical glyceryl trinitrate may play an important role in the management of anal fissures, US surgeons say," Australian Doctor, October 4, 1996.	<input type="checkbox"/>	
	6.	HOWES, L.G., "Statutory Declaration: In the Matter of Australian Patent Application No. 708694 in the Name of Cellegy Australia Pty Ltd -and- In the Matter of Opposition thereto by Peter Loder," 2 pages, October 12, 2000, with Curriculum Vitae of Lawrence Guy Howes as Exhibit LGH-1 (26 pages).	<input type="checkbox"/>	
	7.	JONES, I.T., "The solitary rectal ulcer," presentation abstract, May 14, 1993 [Exhibit PBL-11 to the Loder Declaration]	<input type="checkbox"/>	
	8.	KAMM, M.A. et al., "The Sir Alan Parks Physiology Unit," St. Mark's Hospital Year Book, St. Mark's Hospital, London, U.K., 2 pages [Exhibit PBL-14 to the Loder Declaration]	<input type="checkbox"/>	
	9.	KENNEDY, M.L., "Statutory Declaration: In the Matter of Australian Patent Application No. 708694 in the Name of Cellegy Australia Pty Ltd -and- In the Matter of Opposition thereto by Peter Loder," 2 pages, October 12, 2000	<input type="checkbox"/>	
	10.	LODER, P.B., "Statutory Declaration: In the Matter of Australian Patent Application No. 708694 in the Name of Koren Laboratories Pty Limited -and- In the Matter of Opposition thereto by Peter Loder," October 11, 2000, 37 pages; with Exhibits PBL-2, 5, 8, 9, 11, 12, 14, 19, and 22-25.	<input type="checkbox"/>	
	11.	LODER, P.B., "Curriculum Vitae of Peter Bruce Loder" October 11, 2000, 14 pages [Exhibit PBL-2 to the Loder Declaration]	<input type="checkbox"/>	
	12.	LODER, P.B., "Application for Ethical Approval of Pilot Study" October 11, 2000, 15 pages [Exhibit PBL-8 to the Loder Declaration]	<input type="checkbox"/>	
	13.	LODER, P.B. et al., "Reversible chemical sphincterotomy by topical application of glyceryl trinitrate (GTN)," St. Mark's Hospital, London, U.K., presentation abstract, May 13, 1993 [Exhibit PBL-11 to the Loder Declaration]	<input type="checkbox"/>	
Examiner Signature				Date Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	10/669,099
				Filing Date	September 22, 2003
				First Named Inventor	Gorfine, Stephen R.
				Art Unit	1655
				Examiner Name	Tate, Christopher Robin
Sheet	3	of	4	Attorney Docket Number	010692-004532US

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²	
	14.	LODER, P.B. et al., "A new den for the winged lion: St. Mark's at Northwick Park," St. Mark's Hospital, London, U.K., presentation abstract, May 14, 1993 [Exhibit PBL-11 to the Loder Declaration]	<input type="checkbox"/>	
	15.	LODER, P.B., Presentation Slides, May 13-14, 1993, 14 pages [Exhibit PBL-12 to the Loder Declaration]	<input type="checkbox"/>	
	16.	LODER, P.B., Letter to Dr. D.Z. Lubowski re discussion of GTN, 2 pages, July 18, 2000 [Exhibit PBL-22 to the Loder Declaration and Exhibit DZL-14 to the Lubowski Declaration]	<input type="checkbox"/>	
	17.	LODER, P.D., Email message to John Scholefield re GTN + Warts, 2 pages, August 1, 1998 [Exhibit PBL-23 to the Loder Declaration]	<input type="checkbox"/>	
	18.	LODER, P.D., Type-written notes re telephone conversations with D. Z. Lubowski, November 11, 1999 and November 28, 1999, 2 pages [Exhibit PBL-25 to the Loder Declaration]	<input type="checkbox"/>	
	19.	LUBOWSKI, D.Z., "Statutory Declaration: In the Matter of Australian Patent Application No. 708694 in the Name of Cellegy Australia Pty Limited -and- In the Matter of Opposition thereto by Peter Bruce Loder," October 16, 2000, 14 pages; with Exhibits DZL-1, 9, and 14]	<input type="checkbox"/>	
	20.	LUBOWSKI, D.Z., "Curriculum Vitae of David Z. Lubowski," 38 pages, October 16, 2000 [Exhibit DZL-1 to the Lubowski Declaration]	<input type="checkbox"/>	
	21.	LUBOWSKI, D.Z. et al., "A radio-isotope study of colonic function during defaecation," St. George Hospital, Sydney, presentation abstract, May 13, 1993 [Exhibit PBL-11 to the Loder Declaration]	<input type="checkbox"/>	
	22.	LUBOWSKI, D.Z., "Anorectal physiology - Is it useful in rectal prolapse?," St. George Hospital, Sydney, presentation abstract, May 14, 1993 [Exhibit PBL-11 to the Loder Declaration]	<input type="checkbox"/>	
	23.	LUBOWSKI, D.Z., Letter to Dr. P. B. Loder re discussion of GTN with reply by Peter B. Loder, 3 pages, July 25, 1998 [Exhibit DZL-14 to the Lubowski Declaration and Exhibit PBL-22 to the Loder Declaration]	<input type="checkbox"/>	
	24.	MARCHEI, C., "Statutory Declaration: In the Matter of Australian Patent Application No. 708694 in the Name of Cellegy Australia Pty Ltd -and- In the Matter of Opposition thereto by Peter Loder," 2 pages, October 11, 2000	<input type="checkbox"/>	
	25.	PHILLIPS, R.K.S., Letters dated October 29, 1998 and May 12, 1998 regarding invitation to lecture at St. Mark's Hospital, 7 pages [Exhibit DZL-9 to the Lubowski Declaration]	<input type="checkbox"/>	
Examiner Signature				Date Considered

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known	
				Application Number	10/669,099
				Filing Date	September 22, 2003
				First Named Inventor	Gorfine, Stephen R.
				Art Unit	1655
Examiner Name	Tate, Christopher Robin				
Sheet	4	of	4	Attorney Docket Number	010692-004532US

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	26.	SCHOLEFIELD, J., Email messages to Peter Loder, including 1 from Peter Stein, regarding Gorfine patent application, 4 pages, April 1, 1997 [Exhibit PBL-19 to the Loder Declaration]	<input type="checkbox"/>
	27.	SCHOUTEN, W.R., "Lateral internal sphincterotomy in the treatment of Hemorrhoids: A clinical and manometric study" Dis Colon Rectum 29:869-72 (1986) [Exhibit PBL-5 to the Loder Declaration]	<input type="checkbox"/>
	28.	STEIN, P.M., Letter to Dr. Peter B. Loder regarding circumstances surrounding meeting, 3 pages, September 18, 2000 [Exhibit PBL-24 to the Loder Declaration]	<input type="checkbox"/>
			<input type="checkbox"/>

Examiner Signature		Date Considered	
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¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.



Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).

FEE TRANSMITTAL
For FY 2006☐ Applicant claims small entity status. See 37 CFR 1.27**TOTAL AMOUNT OF PAYMENT** (\$) 180**Complete if Known**

Application Number	10/669,099
Filing Date	September 22, 2003
First Named Inventor	Gorfine, Stephen R.
Examiner Name	Tate, Christopher Robin
Art Unit	1655
Attorney Docket No.	010692-004532US

METHOD OF PAYMENT (check all that apply)

☐ Check ☐ Credit Card ☐ Money Order ☐ None ☐ Other (please identify): _____
☒ Deposit Account Deposit Account Number: 20-1430 Deposit Account Name: Townsend and Townsend and Crew LLP

For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

☒ Charge fee(s) indicated below ☐ Charge fee(s) indicated below, except for the filing fee
☒ Charge any additional fee(s) or underpayments of fee(s) under 37 CFR 1.16 and 1.17 ☒ Credit any overpayments

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.**FEE CALCULATION (All the fees below are due upon filing or may be subject to a surcharge.)****1. BASIC FILING, SEARCH, AND EXAMINATION FEES**

Application Type	FILING FEES Small Entity		SEARCH FEES Small Entity		EXAMINATION FEES Small Entity		Fees Paid (\$)
	Fee (\$)	Fee (\$)	Fee (\$)	Fee (\$)	Fee (\$)	Fee (\$)	
Utility	300	150	500	250	200	100	
Design	200	100	100	50	130	65	
Plant	200	100	300	150	160	80	
Reissue	300	150	500	250	600	300	
Provisional	200	100	0	0	0	0	

2. EXCESS CLAIM FEES

Fee Description	Fee (\$)	Small Entity Fee (\$)
Each claim over 20 (including Reissues)	50	25
Each independent claim over 3 (including Reissues)	200	100
Multiple dependent claims	360	180
Total Claims		
Extra Claims		
Fee (\$)		
Fee Paid (\$)		

HP = highest number of total claims paid for, if greater than 20

Indep. Claims	Extra Claims	Fee (\$)	Fee Paid (\$)

HP = highest number of independent claims paid for, if greater than 3

3. APPLICATION SIZE FEE

If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof	Fee (\$)	Fee Paid (\$)

- 100 = / 50 = (round up to a whole number) x =

4. OTHER FEE(S)

Non-English Specification, \$130 fee (no small entity discount)

Other (e.g., late filing surcharge): Submission of Information Disclosure Stmt

180

SUBMITTED BY

Signature		Registration No. (Attorney/Agent)	46,946	Telephone	925-472-5000
Name (Print/Type)	Frank J. Mycroft	Date	July 13, 2006		